



**Eastern Visayas Health Research and Development Consortium-  
Ethics Review Committee (EVHRDC-ERC)  
STANDARD OPERATING PROCEDURE**

**CHAPTER 4: DOCUMENTATION AND ARCHIVING**

<b>PREPARING THE MEETING AGENDA</b>	SOP No.	23
	Version No.	02
	Version Date	04-25-2023
	Effective Date	04-30-2023

**1. STATEMENT OF POLICY**

The meeting agenda shall be based on the submissions received on or before the cut-off date. The meeting agenda includes the submitted protocols before the cut-off date which is every 15<sup>th</sup> day of the month. The provisional agenda shall be included in the Notice of Meeting.

**2. OBJECTIVE/S OF THE ACTIVITY**

The preparation of the meeting shall ensure smooth, orderly, inclusive, and efficient conduct of the meeting.

**3. SCOPE AND APPLICABILITY**

In this procedure, the ERC determines which protocols are to be included in the agenda for full review and expedited review, and which topics or protocols are for special meetings. The SOP starts with the preparation of the draft for the meeting agenda and ends with the filing of the final meeting agenda.

**4. ROLES AND RESPONSIBILITIES**

Compliance shall be the responsibility of the ERC Chair, ERC Member Secretary, and ERC Staff Secretary.

**ERC Chair** - sets the agenda and determines the attendees of the meeting.

**ERC Member Secretary** - prepares the draft agenda for the meeting.

**ERC Staff Secretary** - distributes the draft agenda.

## 5. WORKFLOW

ACTIVITY	RESPONSIBILITY
Step 1: Preparation of the draft meeting agenda	ERC Staff Secretary
Step 2: Preparation of the provisional meeting agenda	ERC Chair
Step 3: Distribution of the provisional meeting agenda	ERC Staff Secretary
Step 4: Approval of the provisional agenda	ERC Members
Step 5: Filing of the final agenda	ERC Staff Secretary

## 6. DESCRIPTION OF PROCEDURES

### 6.1 Preparation of the draft meeting agenda

The ERC Staff Secretary, under the supervision of the ERC Chair or Member Secretary, prepares the draft agenda fourteen (14) days before the scheduled full board review meeting and nine (9) working days before the expedited review meeting using **Form 23.1 Provisional Agenda of the Full Board Review Meeting or Form 23.2 Provisional Agenda of the Expedited Review Meeting**. The agenda includes the following:

- 1.1. New Protocols
- 1.2. Review of Protocol Resubmissions
- 1.3. Protocol Amendments
- 1.4. Progress Report
- 1.5 Protocol Deviations / Violations
- 1.6 RNE Reports
- 1.7 SAE and SUSAR Report
- 1.8 Early Study Termination
- 1.9 Continuing Review
- 1.10 Final Reports
- 1.11 Management of Appeals
- 1.12 Site Visits Report
- 1.13 Queries or Complaints
- 1.14 Report of Approved Protocols under Expedited Review
  - 1.14.1 Approved New Protocols
  - 1.14.2 Approved Resubmitted Protocols
- 1.14 Report on Exempt from Review Protocols
- 1.15 Report on SJREB Protocols

### 6.2 Preparation of the provisional meeting agenda

The ERC Chair reviews the draft agenda within 3 working days as the basis of preparing the provisional agenda for inclusion in the **Form 23.1 Provisional**

**Agenda of the Full Board Review Meeting or Form 23.2 Provisional Agenda of the Expedited Review Meeting.**

**6.3 Distribution of the provisional meeting agenda**

The ERC Chair instructs the staff secretary to distribute the meeting agenda to all members via email seven (7) working days before the scheduled meeting. **Form 23.3 Notice of Meeting** is also distributed to all members.

**6.4 Approval of the provisional agenda**

The ERC members approve the provisional agenda during the meeting.

**6.5 Filing of the final agenda**

The staff secretary files the approved meeting agenda in a special folder that contains all meeting agendas in chronological order.

**7. FORMS AND TOOLS**

- Form 23.1 Provisional Agenda of the Full Board Review Meeting
- Form 23.2 Provisional Agenda of the Expedited Review Meeting
- Form 23.3 Notice of Meeting

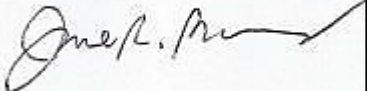

**8. HISTORY**

<b>Version No.</b>	<b>Date (mm/dd/yyyy)</b>	<b>Authors</b>	<b>Main Change</b>
1	11/28/2022	Dr. Jane R. Borrinaga Ms. Sarah B. Delorino Engr. Florentino L. Quiñones Ms. Noreen S. Buhat Fr. Charles Gingco Dr. Jose Carlo K. Del Pilar Ms. Erleta S. Piñero Atty. Alma Sonia Q. Sanchez-Danday Mr. Ricky T. Serrano Mr. Raymond G. Campo	First draft
2	04/25/2023	Dr. Jane R. Borrinaga Ms. Sarah B. Delorino Engr. Florentino L. Quiñones Ms. Noreen S. Buhat Fr. Charles Gingco	Revised description of procedures

		Dr. Jose Carlo K. Del Pilar Ms. Erleta S. Piñero Atty. Alma Sonia Q. Sanchez-Danday Mr. Ricky T. Serrano Mr. Raymond G. Campo	
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**9. REFERENCES**

- World Medical Association Declaration of Helsinki, 2013
- ICH Harmonized Guidelines/Integrated Addendum to ICH E6 (R1): GUIDELINES FOR GOOD CLINICAL PRACTICE E6 (R2)
- WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011
- International Ethical Guidelines for Health-related involving Humans (CIOMS) 2016
- National Ethical Guidelines for Health and Health Related Research 2017
- Philippine Health Research Ethics Board Standard Operating Procedures 2020
- BatMC RERC SOP 2020

Prepared by:	Reviewed and Approved by: 	Approved by: 
<b>ETHICS REVIEW COMMITTEE</b>	<b>DR. JANE R. BORRINAGA, MD, FPCP</b> ERC Chair	<b>EXUPERIA B. SABALBERINO, MD, MPH, CESe</b> EVHRDC Executive Committee Chair
Date: 04-25-2023	Date: 04-25-2023	Date: 04-25-2023